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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,135	10/18/2006	Amar Lulla	PAC/23225 US (4137-00600)	8688
30652	7590	06/13/2011	EXAMINER	
CONLEY ROSE, P.C. 5601 GRANITE PARKWAY, SUITE 750 PLANO, TX 75024			WINTERBERG, NISSA M	
			ART UNIT	PAPER NUMBER
			1618	
			MAIL DATE	DELIVERY MODE
			06/13/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/574,135

Applicant(s)

LULLA ET AL.

Examiner

NISSA WESTERBERG

Art Unit

1618

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 01 June 2011 FAILS TO PLACE THIS APPLICATION IN COMPLIANCE FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-8, 11-14, 18-33 and 53

Claim(s) withdrawn from consideration: 9 and 10

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/Nissa M Westerberg/
Primary Examiner, Art Unit 1618

Continuation of 11. does NOT place the application in condition for allowance because: The rejection of claims 1 - 8, 11 - 22, 25 - 32 and 53 under 35 U.S.C. 103(a) as being unpatentable over Katdare et al. (WO 95/29679) in view of Adamski et al. (WO 01/85176) is maintained for the reasons of record set forth in the Office Action mailed April 5, 2011 and those set forth below.

The claim amendment imports the limitation from dependent claim 54 into independent claim 1.

Applicants traverse this rejection on the grounds that the limitation of the carbohydrate alcohol being between 15 wt. % and 40 wt. % of the formulation is not taught by the applied references. Only Adamski discloses the use of a specific amount of carbohydrate alcohol as the range of diluent encompassed by the combination is 30 - 80% (*arguendo*). The amount of carbohydrate alcohol in Adamski discloses a range of mannitol of 50-80%, which is outside the presently claimed range. The statement in the previous Office Action about lower amounts of mannitol being used when a second diluent is present is conclusory and that Adamski does not reduce the amount of mannitol in the presence of additional diluents.

These arguments are unpersuasive. The range of mannitol set forth in Adamski is only a preferred range (p 6, ln 19) and the amounts of the various ingredients in the pharmaceutical composition are a results effective parameter that the person of ordinary skill in the art would routinely optimize (see p 3 - 4 of previous Office Action). The criticality of this range has not established by Applicant.

The rejections of claims 23, 24 and 33 as being unpatentable over Katdare and Adamski further in view of Flash-Ner-Barak et al. (WO 2002/00204) is not argued by Applicant and thus is maintained for the reasons set forth above in regards to Adamski and Katdare above and for the reasons of record set forth in the Office Action mailed April 5, 2011.